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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/187,669	11/05/1998	EDUARDO MARBAN	47728	3339

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DIKE BRONSTEIN ROBERTS & CUSHMAN
Intellectual Property Practice Group
EDWARDS & ANGELL
P.O. Box 9169
BOSTON, MA 02209

EXAMINER	
LEFFERS JR, GERALD G	

ART UNIT	PAPER NUMBER
1636	15

DATE MAILED: 02/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/187,669	MARBAN, EDUARDO	
	Examiner	Art Unit	
	Gerald Leffers	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *16-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 29-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☒ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicant's amendment, filed 12-10-02 as Paper No. 13, in which a new paper copy of the sequence listing, corresponding CRF and attorney's statement were filed. The CRF and paper copy of the sequence listing have been entered into the file. Applicant is hereby notified that the Brief Description of the Drawings has been modified to include sequence identifiers for the sequences shown in Figure 3.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-15 and 29-31) in Paper No. 8, filed 3/2/01, is acknowledged. The traversal is on the ground(s) that the two groups identified in the Written Restriction Requirement have the same classification at both the class and subclass levels. This is not found persuasive because the subject matter of Group II would necessarily require a non-patent literature search that is not necessarily required for the claims of Group I (e.g. ion channel proteins, model systems for cardiac arrhythmia, etc.).

The requirement is still deemed proper and is therefore made FINAL.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (i.e. page 21, line 24). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 and 29-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the metes and bounds of the terms "selected protein" and "selected cells" are unclear. It is unclear as the claim is currently written if the step of "selection" is part of the claim methodology and what characteristics are considered in order for a particular protein or cell to be selected. For example, the phrase implies some sort of "selection" process for cells expressing a particular protein as opposed to cells which do not express the particular protein (e.g. a selectable marker). It would be remedial to amend the claim language to more clearly recite the characteristics for which the particular proteins and cells of the invention are "selected" and how the "selected" proteins and/or cells figure in the steps of the claimed method (e.g. are the "selected" proteins drug targets?).

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The metes and bounds of the phrase "...analyzing the result of expression of the protein to thereby predict the effect of the drug candidate compound..." are unclear. This phrase appears to be nothing more than a recitation of a desired outcome without any methods steps reciting how the desired outcome is to be achieved. The omitted steps are: any step or combination of steps whereby the results of expressing the selected protein in the host cell is

correlated to possible effects of a drug candidate compound. Also, there is no step or recitation that links the drug candidate compound to the expressed protein. It would be remedial to amend the claim language to include steps which bridge the gap between expression of the selected protein and predicting the effect of a candidate compound.

Claim 2 is vague and indefinite in that the metes and bounds of the phrase "...wherein the result of the protein expression is analyzed to identify a molecular target of the drug candidate compound..." are unclear. It is unclear how one could identify a molecular target of the drug candidate compound when there is no linkage anywhere in the claim language of the candidate drug compound and protein expression. Again, it would be remedial to amend the claim to clearly indicate the relationship between the candidate drug compound and the expression of the selected protein.

Claim 7 is vague and indefinite in that the metes and bounds of the phrase "...analyzing the result of expression of the target protein..." are unclear. The phrase is unclear in that the claim does not spell out how one should carry out the analysis and with what purpose. For example, what criteria would have to be satisfied for the target protein to be considered a "potential drug target protein"? It would be remedial to amend the claim language to clearly indicate what parameters should be analyzed regarding expression of the target protein and the end to which the analysis is to be directed (e.g. determination of the potential of a target polypeptide as a drug target).

Claim 14 is vague and indefinite in that the metes and bounds of the phrase "...the target protein is capably of specifically forming a binding complex with at least one other protein..." are unclear. First, the phrase "capably of" is grammatically incorrect. Second, it is unclear

under what conditions the target protein is "capable of specifically" forming a binding complex. Also, what exactly constitutes "specifically forming" a binding complex? Finally, it is unclear as the claim is written as to whether the "other" protein is necessarily another type of protein (e.g. a completely different protein) or also includes proteins of the same type (e.g. the same protein in a homomultimeric complex, or similar proteins that have been modified).

Claim 29 is vague and indefinite in that the metes and bounds of the terms "selected protein" and "selected cells" are unclear. It is unclear as the claim is currently written if the step of "selection" is part of the claim methodology and what characteristics are considered in order for a particular protein or cell to be selected. For example, the phrase implies some sort of "selection" process for cells expressing a particular protein as opposed to cells which do not express the particular protein (e.g. a selectable marker). It would be remedial to amend the claim language to more clearly recite the characteristics for which the particular proteins and cells of the invention are "selected" and how the "selected" proteins and/or cells figure in the steps of the claimed method (e.g. are the "selected" proteins drug targets?).

Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The metes and bounds of the phrase "...analyzing the result of expression of the protein to thereby predict the effect of the drug candidate compound..." are unclear. This phrase appears to be nothing more than a recitation of a desired outcome without any methods steps reciting how the desired outcome is to be achieved. The omitted steps are: any step or combination of steps whereby the results of expressing the selected protein in the host cell is correlated to possible effects of a drug candidate compound. Also, there is no step or recitation

that links the drug candidate compound to the expressed protein. It would be remedial to amend the claim language to include steps which bridge the gap between expression of the selected protein and predicting the effect of a candidate compound.

Claim 31 provides for the use of "standard" drug discovery strategy and identified proteins, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 31 is also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined

was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-15 and 29-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Kamb (U.S. Patent No. 5,955,275; see the entire document).

Kamb teaches methods for identifying nucleic acid sequences that affect a cellular phenotype. The methods use a reporter gene whose level of expression correlates with the phenotype. An expression library is introduced into the cells and those cells exhibiting changes in reporter expression level are selected (e.g. Abstract). The expression library of the invention preferably expresses sequences encoding protein fragments, peptides or proteins that are termed "perturbagens" (column 3, lines 0-26). Host cells of the invention can be of several types, including human cells isolated from tissues and cancers (e.g. melanoma, colon cancer, etc.). Following expression, cells are selected based upon the decrease or increase in expression of the reporter protein (which can be considered a "target" polypeptide) upon expression of the library members (e.g. column 3, lines 20-26). The patent describes "perturbagens" as molecules that act in a transdominant mode to interfere with the function of endogenous cellular components. Perturbagens are typically proteinacious but may also be nucleic acids (e.g. antisense). Thus, the perturbagens of the patent can be considered "selected" or "target" proteins. Kamb teaches that one manner in which perturbagens can exert their effect is by forming a binding complex between the wildtype target polypeptide and a perturbagen that is a fragment of the wildtype protein. Such a binding complex, comprising an altered form of the wildtype protein with the

wildtype protein, is expected to behave in a manner similar to a small molecule inhibitor of the wildtype protein (e.g. Figures 1A-1C; columns 4-5, bridging paragraph). A perturbagen functioning in such a manner and selected for its ability to increase or decrease the expression of a reporter protein would necessarily be selected based upon its ability to "mimic" or "predict" the effect a drug compound. A perturbagen functioning in this manner would also necessarily constitute a "dominant negative" effect as defined in the specification (e.g. pages 12-13 of the instant specification-bridging paragraph). Kamb teaches that the perturbagen targets proteins are as interesting as the perturbagens themselves and can be readily identified by standard techniques (e.g. two-hybrid technologies) (e.g. column 15, lines 11-40).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr.
Examiner
Art Unit 1636

ggl
February 24, 2002

DAVID GUZO
PRIMARY EXAMINER